Interview Summary

In the Examiner's Interview Summary, dated August 17, 1999, (Paper No. 5) the Examiner stated that, "there was an agreement that the present claim language of the stem end (30') of the invention could not overcome the reference Morrey et al." (sic.). Applicants disagree with the Examiner's statement and respectfully submit that there was no agreement that the original claim language could not overcome the Morrey et al. (U.S. Patent No. 5,433,055; hereinafter referred to as "Morrey") reference.

Claim Rejections - 35 U.S.C. §103(a)

The Examiner has rejected claims 1-6 under 35 U.S.C. §103(a) as being unpatentable over Morrey in view of Caldarise et al. (U.S. Patent No. 5,897,592; hereinafter referred to as "Caldarise") and further in view of Gradinger et al. (U.S. Patent No. 5,433,750; hereinafter referred to as "Gradinger"). Applicants traverse the Examiner's rejection as applied to the amended claims.

Applicants' invention is directed to an endoprosthesis that is fixed in the neck of the femur only as shown in attached Fig. B. The special shape of the present invention in combination with the outer lattice structure enables the artificial hip joint to be implanted with only a minimal amount of resection of natural bone material.

Referring to the attached Fig. A, many of the artificial hip joint devices of the prior art have a bend that is placed closer to the proximal end of the device than that of the present invention and have distal ends that lie in the intramedular channel of the femur. These artificial hip joints require a larger amount of bone resection during implantation than that of the

present invention. Attached Fig. C clearly shows the difference between the present invention and hip joints that are positioned in the intramedular channel, such as the Morrey device. Specifically, the amount of bone removed during implantation of artificial hip joints is significantly reduced by the present invention which is implanted in the neck of the femur only.

The reduced amount of bone resection is particular critical when the artificial hip joint is implanted in a relatively young person who is likely to need to have the artificial hip replaced at least one time. Each replacement of an artificial hip results in further bone being removed from the femur and thus, further weakens the femur. Accordingly, it is critically important to preserve a maximum amount of femur bone during the first implantation. Additionally, the curved distal end of the artificial hip joint of the present invention and the ability of the joint to be positioned in only the neck of the femur results in improved force distribution throughout the femur and reduces the amount of abnormally high stresses that are experienced by the femur bone.

Applicants' claim 1 recites, *inter alia*, "a distal end of the shell being bent caudally and constructed as a stem end." Webster's dictionary defines caudally as, "1. Anat., Zool. of, at, or near the tail or the posterior end of the body" (Webster's Encyclopedic Unabridged Dictionary of the English Language, 1994 Deluxe Edition) (Emphasis added). Accordingly, Applicants' claim 1 positively recites a shell having a distal end that is bent and that forms a stem end.

Morrey discloses an artificial hip joint of the type shown in the attached Fig. A. The Morrey joint has a stem that is properly positioned in the intramedular channel of the femur. The bend in the Morrey reference is not caudal, i.e., at or near the distal end, but is closer to the medial portion of the implant stem. The distal end of the stem portion is tapered in an elongated

fashion and terminates at a radiused end portion. In the coronal plane, the tapered portion is angulated in a valgus direction from the axis of the main body of the stem portion. This enables the stem portion to be oriented and positioned in the bone tissue during the insertion thereof (specification, column 3, lines 10-16). There is no disclosure, teaching or suggestion to bend the Morrey hip joint stem portion at a distal end that forms a stem end as in the present invention. Such a bend would clearly result in the distal end of the Morrey joint bending away from the intramedular channel in which the stem is generally positioned. Additionally, it is not possible to implant the Morrey artificial hip joint in only the neck of the femur.

Gradinger discloses an artificial hip joint that uses a three dimensional lattice structure having different mesh sizes. The Gradinger hip joint is of the type shown in Fig. A and is meant to be positioned in the intramedular channel in the femur. There is no disclosure, teaching or suggestion to bend the Gradinger hip joint caudally at a distal end that forms a stem end as such a bend would cause the distal end of the Gradinger joint to bend away from the intramedular channel in which the stem is generally positioned. Additionally, it is not possible to implant the Gradinger artificial hip joint in only the neck of the femur.

Caldarise discloses an artificial hip joint having a macrotextured surface. The Caldarise hip joint is of the type shown in Fig. A and is meant to be positioned in the intramedular channel in the femur. There is no disclosure, teaching or suggestion to bend the Caldarise hip joint caudally at a distal end that forms a stem end as such a bend would cause the distal end of the Caldarise joint to bend away from the intramedular channel in which the stem is generally positioned. Additionally, it is not possible to implant the Morrey artificial hip joint in only the neck of the femur.

The preamble of a claim must properly be considered when phraseology in the preamble limits the structure of the claimed article, as explained below:

> In order to limit the claim, the preamble must be essential to point out the invention defined by the claim. . . . In claims directed to articles and apparatus, any phraseology in the preamble that limits the structure of that article or apparatus must be given weight.
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> . . .
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> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim [MPEP 2111.02 (emphasis added)].

Applicants respectfully submit that the phraseology of the preamble of claim 1 which recites that the artificial hip joint is "adapted to be implanted in only the neck of the femur" limits the structure of the claimed apparatus. Additionally, Applicants respectfully submit that the above-mentioned phraseology results in a structural difference between the claimed invention and the prior art cited by the Examiner in forming this rejection. For example, the angle between the neck which supports the head of the artificial hip joint and the longitudinal axis of the stem portion of the joint must be within a given range if the head of the joint is to fit in the corresponding hip socket while the stem of the joint is implanted in the more lateral orientation necessary to implant the stem in only the neck of the femur. Furthermore, Applicants respectfully submit that the prior art cited by the Examiner in this rejection is not capable of

being implanted in only the neck of the femur. Accordingly, Applicants respectfully submit that the recitation "adapted to be implanted in only the neck of the femur" must be given patentable weight.

To properly combine and modify references to form a section 103 rejection:

> The proposed modification cannot change the principle of operation of a reference. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie obvious* [MPEP 2143.01 (emphasis added)].

Morrey cannot properly be used to form a combination to reject Applicants' claimed invention because the modifications to Morrey necessary to form Applicants' claimed device will change the principle of operation, i.e., to be implanted along the longitudinal axis of the femur, of the Morrey device. Referring to Fig. 2, the angle between the neck portion 13 and the tapered portion 17 is about seventy degrees. As shown in Fig. 6, the cavity 113 that receives the tapered portion 17 is centrally longitudinally aligned with the proximal end of the stem portion 50. Accordingly, once the head and neck portion 10 is attached to the stem portion 50, the neck portion 13 forms an angle of about seventy degrees with the longitudinal axis of the proximal end of the shell 50. Due to the angle between the head portion 12 and the shell 50, the stem of the Morrey device must be positioned along the longitudinal axis of the femur for the head portion 12 and the neck portion 13 to be properly aligned with the corresponding hip socket. Thus, it is the Morrey device's principle of operation to be implanted along the longitudinal axis of the femur in a manner similar to that shown in the Attached Fig. A.

Accordingly, if the Morrey device were modified to produce Applicants' hip joint, then the Morrey device could no longer be implanted substantially along the longitudinal axis of the femur and the principle of operation of the Morrey device would be changed. Applicants respectfully submit that Morrey cannot be used as part of a combination to render claim 1 prima facie obvious.

Caldarise cannot properly be used to form a combination to reject Applicants' claimed invention because the modifications to Caldarise necessary to form Applicants' claimed device will change the principle of operation, i.e., to be implanted along the longitudinal axis of the femur, of the Caldarise device. Referring to Fig. 1A, the angle between the head and the longitudinal axis of the stem clearly illustrates that the Caldarise device must be positioned along the longitudinal axis of the femur. Thus, it is the Caldarise device's principle of operation to be implanted along the longitudinal axis of the femur in a manner similar to that shown in the Attached Fig. A. If the Caldarise device were modified to produce Applicants' hip joint, then the Caldarise device could no longer be implanted substantially along the longitudinal axis of the femur and the principle of operation of the Caldarise device would be changed. Accordingly, Applicants respectfully submit that Caldarise cannot be used as part of a combination to render claim 1 prima facie obvious.

Gradinger cannot properly be used to form a combination to reject Applicants' claimed invention because the modifications to Gradinger necessary to form Applicants' claimed device will change the principle of operation, i.e., to be implanted along the longitudinal axis of the femur, of the Gradinger device. Referring to Fig. 1A, the angle between the head and the longitudinal axis of the stem clearly illustrates that the Gradinger device must be positioned along the longitudinal axis of the femur. Thus, it is the Gradinger device's principle of operation

to be implanted along the longitudinal axis of the femur in a manner similar to that shown in the Attached Fig. A. If the Gradinger device were modified to produce Applicants' hip joint, then the Gradinger device could no longer be implanted substantially along the longitudinal axis of the femur and the principle of operation of the Gradinger device would be changed. Accordingly, Applicants respectfully submit that Gradinger cannot be used as part of a combination to render claim 1 prima facie obvious.

To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations" (MPEP § 2142).

Even assuming, *arguendo*, that the combination cited by the Examiner is proper, the combination fails to disclose Applicants' element, recited in claim 1, of, "a distal end of the shell being bent caudally **and** constructed as a stem end" (Emphasis added). Morrey discloses a hip joint having a bend. However, Morrey does not disclose a distal end **that is bent caudally and that forms a stem end**. Gradinger discloses a hip implant that has a slight gradual bend and a straight stem end that is not bent caudally. Caldarise discloses a hip joint having a straight stem that has a stem end that is not bent caudally. Accordingly, Applicants respectfully submit that none of the references cited by the Examiner disclose the element recited in claim 1 of a caudally bent stem end. Furthermore, none of the cited references have the advantage of requiring a reduced amount of resection of bone material which flows directly from the claimed structure of Applicants' claim 1.

Even assuming, *arguendo*, that the combination cited by the Examiner is proper, the combination fails to disclose Applicants' element, recited in the preamble of claim 1, of, "an artificial hip joint adapted to be implanted in only the neck of the femur." None of the references used to form this rejection disclose, teach, or suggest an artificial hip joint that is implanted only

in the neck of the femur. Applicants respectfully submit that claim 1 is patentable over the combination of Morrey, Caldarise, and Gradinger. Additionally, claims 2-6 each depend, directly or indirectly, on claim 1 and, accordingly, are also patentable over the combination cited by the Examiner.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the section 103 rejection of claims 1-6.

New Claims

Independent claims 7 and 8 have been added to the application. Claim 7 is expressly directed to a "femur endoprosthesis for an artificial hip joint adapted to be implanted in only the neck of the femur." Additionally, claim 7 recites, *inter alia*, "the shell being continuously bent throughout a distal portion, including a distal end, of the shell to form a curved stem end (30') . . . the stem end (30') including a concave section adapted to be generally aligned with the longitudinal axis of the femur bone." Claim 8 is directed to a method of implanting a femur endoprosthesis for an artificial hip joint adapted to be implanted in only the neck of the femur.

If the Examiner believes that any additional formal matters need to be addressed in order to place this application in condition for allowance, the Examiner is respectfully invited to contact the undersigned, by telephone, at the Examiner's convenience.

Conclusion

In view of the foregoing Amendment and Remarks, Applicants respectfully submit that the present application, including claims 1-8, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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(Date)

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